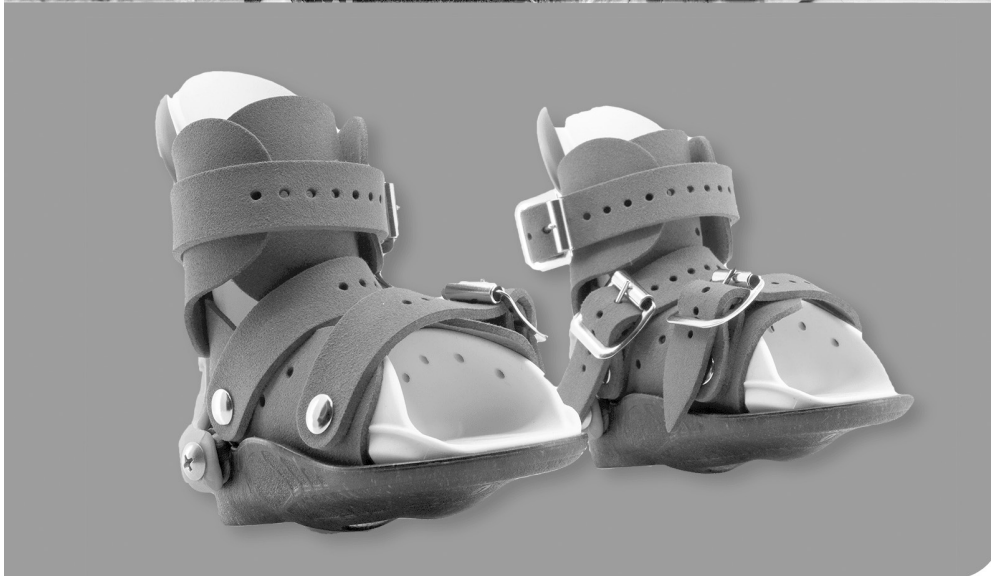




ORTHOPAEDICS



USER INSTRUCTIONS

Mitchell Ponseti® Ankle Foot Orthotic (AFO) and Ponseti® Abduction Brace



MD Orthopaedics, Inc.
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All pertinent state, regional, and local safety regulations must be observed when using this product. For reasons of safety and to help ensure compliance with documented system data, only the manufacturer shall perform repairs to components.

When devices are used for applications with technical safety requirements, the relevant instructions must be followed. Failure to observe this information can result in injury or equipment damage.

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General Notice: Some product names used in this manual are used for identification purposes only and may be trademarks of their respective companies.

1 PREFACE

1.1 Intended Purpose

The **Mitchell Ponseti® Ankle Foot Orthotic (AFO)** and **Ponseti® Abduction Brace** is an ankle-foot orthosis (brace) intended for use in the Ponseti Method of treatment for the correction of Congenital Talipes Equinovarus (CTEV) in infants and children less than or equal to eight years of age. The brace is intended to prevent relapse (equinus and varus deformity of the heel).

The AFO is to be prescribed by a physician trained in the Ponseti Method of clubfoot treatment and is typically worn for 23 hours a day for three months after casting and then during night-time and naptime for up to four years.

A clinical orthotist, also trained in the Ponseti Method, may assist the physician in determining the correct size of the AFO for the child. The orthotist may also train the child's parents and families in the right way to put the AFO onto the child's foot, what cues may indicate poor fit or other issues, and how to determine it is time to move to the next size.

Other members of the clinical team trained in the Ponseti Method – nurses, physician assistants, or other licensed healthcare professionals – may also train parents on the proper use of the AFO and make any necessary adjustments in fit or sizing.

The child's parents or family or other designated caretaker are responsible for adhering to the prescribed Ponseti Method treatment regimen of 23 hours a day for three months, then during sleep and during naptime for the next four years or until the physician indicates the device is no longer needed.

1.2 Target Patient Group and Intended Users

The MD Orthopaedics **Mitchell Ponseti® Ankle Foot Orthotic (AFO)** and **Ponseti® Abduction Brace** is designed to be worn by a child (≤8) years of age with clubfoot after the casting portion of treatment is complete.

This document is intended for the physician, orthotist, clinical team, parents, and families of children receiving treatment with the **Mitchell Ponseti® Ankle Foot Orthotic (AFO)** and **Ponseti® Abduction Brace**.

1.3 Clinical Benefits

The Ponseti Method is a non-surgical clubfoot treatment process developed by Dr. Ignacio Ponseti. The method utilizes gentle manipulation and casting to gradually move the foot into the correct position. Each week the cast is removed, the foot carefully manipulated into the next position, and a new cast is applied. This process continues for up to 6 to 8 weeks.

Following the casting period, the feet are held in the proper position using a foot abduction brace (FAB). The brace is comprised of the Ankle Foot Orthotic (AFO) and the connecting, abduction bar. The brace is typically worn for 23 hours a day for three months, then worn at night and during naptime for up to four years or as prescribed by a physician to ensure the correction holds.

With proper treatment and adherence to the bracing protocol prescribed by the physician, it is expected that most cases of clubfoot can be corrected by the time the child reaches 4 or 5 years of age.

MD Orthopaedics does not provide medical treatment, advice, or information. Information about the risks and benefits of medical treatment, including treatment that involves the use of MD Orthopaedics products should be provided solely by the physician or other qualified health care providers treating your child. If you have questions about your child's treatment, it is important for you to discuss those questions with the appropriate health care provider.

1.4 Explanation of Safety Warnings



Caution indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury.



Indicates information considered important, but not hazard-related.

1.5 Retention Instructions

Read and understand this manual and its safety instructions before using this product. Failure to do so can result in injury.

Follow all the instructions.

The product shall only be used by persons who have fully read and understand the contents of this user manual.

Ensure that each person who uses the product has read these warnings and instructions and follows them.

The manufacturer is not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with the safety instructions. In such cases, the warranty will be voided.

This policy / warranty is non-transferable and covers normal wear and tear only. Altering the product and after-market modifications will void the warranty. Please contact us if you experience problems not outlined in this policy. Atypical matters will be handled on a case-by-case basis.

1.6 Obtaining Documentation and Information

1.6.1 Ordering Documentation

Additional documentation, user instructions and technical information can be ordered by calling MD Orthopaedics at 1-877-766-7384.

1.6.2 Other languages

Instructions for Use (IFU) manuals are available in other languages.

1.6.3 Documentation Feedback

If you are reading MD Orthopaedics product documentation on the internet, any comments can be submitted on the support website. Comments can also be sent to info@mdorthopaedics.com. We appreciate your comments.

1.6.4 Support and service

For questions, information, technical assistance or to order user instructions, please contact:

MD Orthopaedics, Inc.
604 North Parkway Street
Wayland, IA 52654 USA
www.mdorthopaedics.com
1-877-766-7384

1.6.5 Name and address of the manufacturer

The following natural or legal person makes the device, to which this user manual applies, suitable for use within the European Union and is the manufacturer of the device:

The **Mitchell Ponseti® Ankle Foot Orthotic** and **Ponseti® Abduction Brace** are manufactured by:

MD Orthopaedics, Inc.
604 North Parkway Street
Wayland, IA 52654 USA
www.mdorthopaedics.com
1-877-766-7384

2 DESCRIPTION OF THE PRODUCT

2.1 Intended Use and Reasonably Foreseeable Misuse


The **Mitchell Ponseti® Ankle Foot Orthotic** is a Class I medical device intended for use only on children whose clubfoot is being corrected with the Ponseti Method of treatment, and only as prescribed by a physician fully trained in the Ponseti Method.

The **Mitchell Ponseti® Ankle Foot Orthotic** shall not be used without prescription by a physician trained in the Ponseti method and is to be used only as prescribed.

The **Mitchell Ponseti® Ankle Foot Orthotic** shall not be used to treat any other orthopedic condition other than clubfoot unless otherwise prescribed by the physician or orthotist.

The **Mitchell Ponseti® Ankle Foot Orthotic** shall be used with the following original accessories and components only:

- **Ponseti® Adjustable Bar**
 - Available with either 10 or 15 degrees of dorsiflexion.
- **Mitchell Spring Assist Dobbs Bar**
- **Pressure Saddles**
- **Bar Covers**

 Education on proper brace application and troubleshooting for skin issues is critical to ensure your child's clubfoot correction is effective. DO NOT USE this device without first being trained by your physician or clinical team. Contact Customer Support for assistance in locating training resources.

2.2 Sterilization State and Method

Not applicable, as the **Mitchell Ponseti® Ankle Foot Orthotic** is not a sterile product.

2.3 Summary of Safety and Clinical Performance


The **Mitchell Ponseti® Ankle Foot Orthotic** is a Class I, non-implantable device. Therefore, a Summary of Safety and Clinical Performance is not required.


2.4 Technical Characteristics

The **Mitchell Ponseti® AFO** was designed with a soft, contoured elastomeric liner to cushion and hold the child's foot in place. Straps and a body made from a ductile synthetic suede conform to the shape of the foot for added comfort and stability. The AFO has openings on the side to add ventilation and keep the foot cool, and a porthole in the heel socket to help guide proper placement of the heel in the AFO.

NOTE: Socks are **required** to eliminate skin contact with product.

The **Ponseti® Abduction Bar** was designed to be easily adjustable to the shoulder width of the child. The Quick Release clips make it easy for the bar to be attached and removed from the AFOs as needed for clothing and diaper changes, etc.

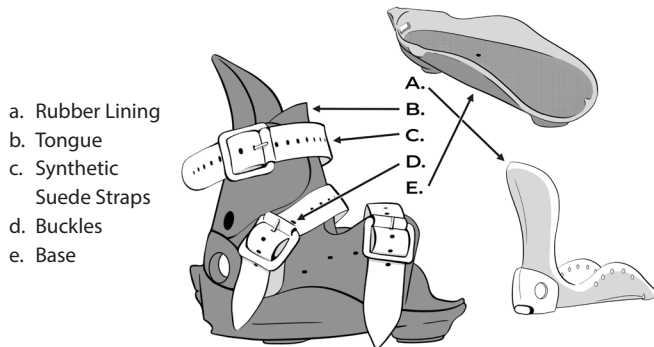
 The length of the foot should be measured from the heel to tip of big toe. Do not add growing room as this is allowed for in the table below.

 The AFOs on Preemie 1, 2 are permanently attached to an adjustable bar.

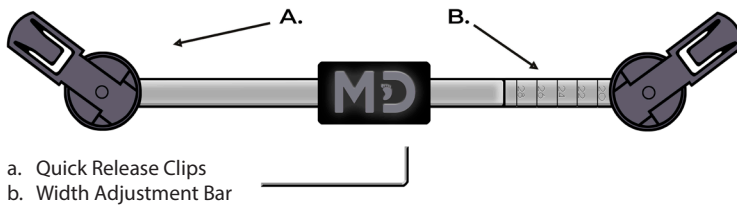
Foot Length (mm)	Size (US)	Size (UK)	Size (EU)
60 to 62	Preemie 1	-	-
63 to 66	Preemie 2	-	-
67 to 70	0000	-	-
71 to 75	000	-	-
76 to 80	00	-	-
81 to 87	0	-	-
88 to 92	1	0.5	16
93 to 102	2	1	17
103 to 112	3	2	18
113 to 122	4	3	19
123 to 132	5	4	20
133 to 142	6	5	22
143 to 152	7	6	23
153 to 162	8	7	24
163 to 172	9	8	25
173 to 182	10	9	27
183 to 192	11	10	28
193 to 202	12	11	30

Ponseti® Abduction Bar Sizes	Minimum Width (cm)	Maximum Width (cm)
Extra Short	17.3	25
Short	20	30
Long	23.5	37.8

2.4.1 Mitchell Ponseti® Ankle Foot Orthotic



2.4.2 Ponseti® Abduction Bar



- a. Quick Release Clips
- b. Width Adjustment Bar

A hex key (wrench) is also included, for making adjustments of the abduction bar as described in section 4.3.

3 SAFETY INSTRUCTIONS

Use the **Mitchell Ponseti® Ankle Foot Orthotic (AFO)** and **Ponseti® Abduction Brace** only in accordance with these instructions and as directed by your physician or other member of the clinical team.

Improper application of the AFO or bar can lead to skin irritation, sores, and blisters.

Socks are **required** to eliminate skin contact with product and prevent skin irritation and blisters.

Consult your physician or clinical team immediately if the child is experiencing pain, blisters, sores, or if the AFO is visibly slipping on the child's foot.

Do not bend the bar or allow children to walk with the bar attached. Bending of the bar may compromise therapeutic value and lead to breakage in use, which may cause harm to the patient.

IMPORTANT: Ensure the dressing area is well lit and free from distraction to ensure you apply the AFO properly. Improper application of the AFO or bar can lead to skin irritation, sores, and blisters.

 **Read and understand this manual and its safety instructions before using this product. Failure to do so can result in injury.**

3.1 How to Use the Product Safely

3.1.1 Technical life span

- All parts were designed to service the entire life cycle of a single patient, with normal use.
- On average, each AFO will last 3-9 months. Some children grow rapidly and will need a replacement in three months. As the child's growth rate slows, more time can be expected.
- The bars are adjustable and should last approximately 2-3 iterations of AFOs. The bar width should be periodically checked and adjusted to match the child's shoulder width or as recommended by your physician or orthotist.

3.1.2 Safety information related to the intended use and reasonably foreseeable misuse.

- Use the **Mitchell Ponseti® Ankle Foot Orthotic** and **Ponseti® Abduction Brace** only in accordance with these instructions and as directed by your physician or other member of the clinical team.
- Consult your physician or clinical team immediately if the child is experiencing pain, blisters, sores, or if they are not in good condition or do not correctly fit the child.
- Do not overtighten the adjusting screws.
- Do not use the **Mitchell Ponseti® Ankle Foot Orthotic** and **Ponseti® Abduction Brace** if it is not in good condition or does not correctly fit the child.
- Protect your child, yourself, and your furniture from being hit by the bar when the child is wearing it. It is recommended to pad the bar with a **Ponseti®** bar cover.

3.1.3 Product limitations and restrictions and contraindications

- Do not bend the bar or allow children to walk with the bar attached. Bending of the bar may compromise therapeutic value and lead to breakage in use, which may cause harm to the patient.
- Do not use the **Mitchell Ponseti® Ankle Foot Orthotic** if it is not in good condition or does not correctly fit the child.
- The **Mitchell Ponseti® Ankle Foot Orthotic** shall not be used without prescription by a physician trained in the Ponseti Method and is to be used only as prescribed.
- The **Mitchell Ponseti® Ankle Foot Orthotic** shall not be used to treat any other orthopedic condition other than clubfoot unless otherwise prescribed by the physician or orthotist.

3.1.4 Safety information when using the device in combination with other devices

- The **Mitchell Ponseti® Ankle Foot Orthotic** shall be used with the following original accessories and components only:
 - **Ponseti® Abduction Bar**
 - **Mitchell Spring Assist Dobbs Bar**
 - **Pressure Saddles**
 - **Ponseti® Bar Covers**

 Altering the product and/or making after-market modifications will void the warranty and may result in injury.

3.1.5 Safety information regarding the use

- Consult your physician or clinical team immediately if the child is experiencing pain, blisters, sores, or if the AFO is visibly slipping on the child's foot.
- Do not bend the bar or allow children to walk with the bar attached. Bending of the bar may compromise therapeutic value and lead to breakage in use, which may cause harm to the patient.

3.1.6 Safe Disposal

- The **Mitchell Ponseti® Ankle Foot Orthotic** can be disposed of in the regular trash. None of the components of the device are recyclable.

3.2 Potential Health Consequences

It is necessary that the brace be worn 23 hours a day for three months and then 12-14 hours a day (naps and nighttime) for 4 years or as directed by your physician.

Ensure the area is well lit and free from distraction to ensure you apply the AFO properly. Improper application of the AFO or bar can lead to skin irritation, sores, and blisters.

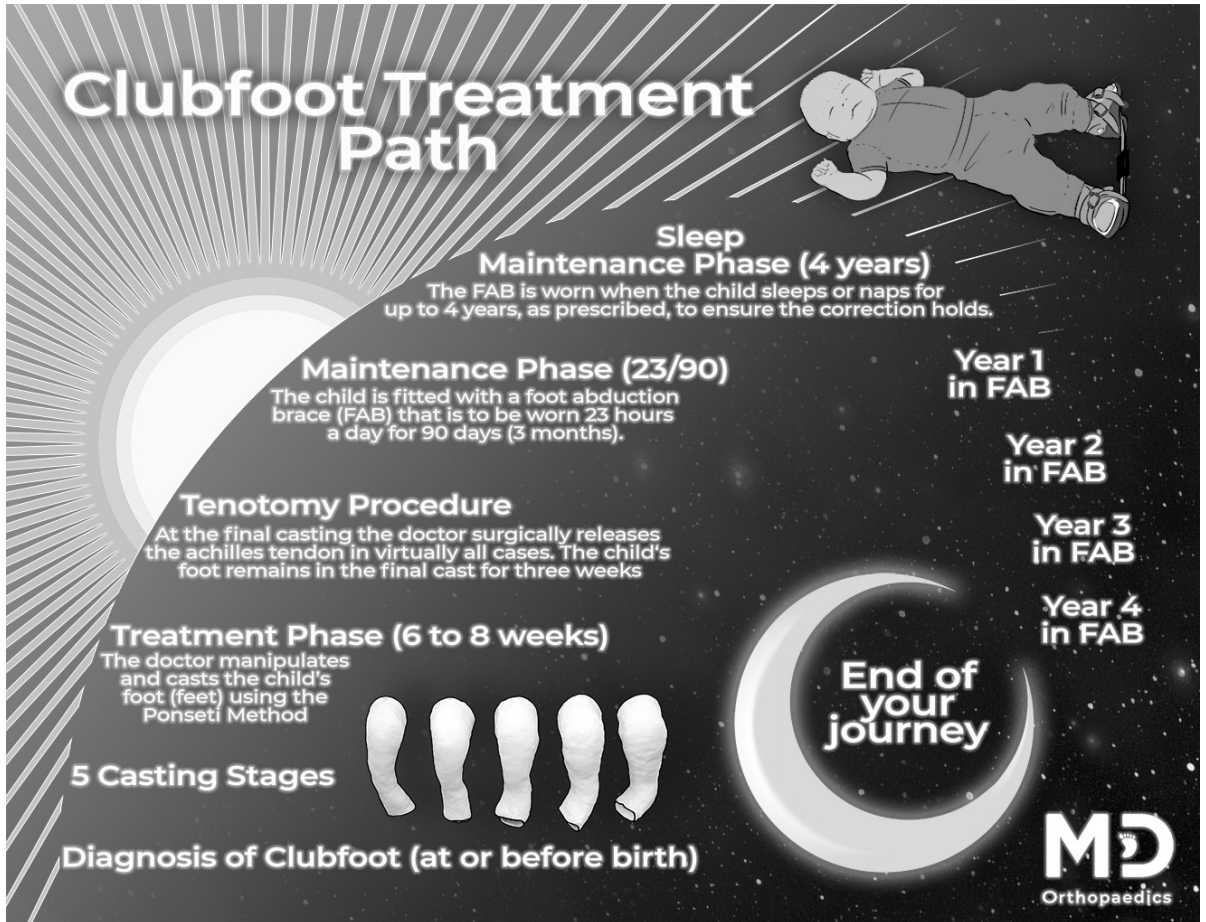
Incorrect use of the AFO may result in relapse of the clubfoot defect or injury to the child's foot. If a user and/or patient experiences any serious incident that has occurred in relation to the device, it should be reported to the MD Orthopaedics, Inc. and the competent authority of the Member State in which the user and/or patient is established.

Please contact MD Orthopaedics if you experience problems not outlined in this policy.

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4 INSTRUCTIONS FOR USE

4.1 Clubfoot Treatment Overview



This infographic provides information — not advice. If you need medical advice, please consult a doctor or other appropriate medical professional.

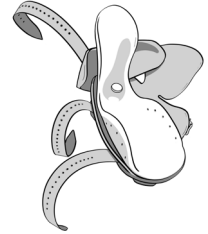
No warranties are given in relationship to the medical information supplied and no liability will be accrued to MD Orthopaedics in the event the user suffers loss because of reliance upon the information provided in this infographic.

4.2 Mitchell Ponseti® AFO



Carefully inspect the AFO before each use. Never use an AFO or bar that is damaged, broken or not functioning properly, as these may injure your child and/or render treatment ineffective. Always use socks with the AFO to prevent direct contact with the skin.

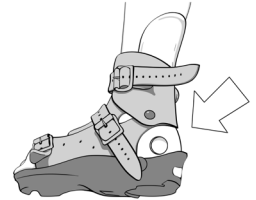
1. Open the AFO so all the suede straps are clear for inserting the foot. Buckles are designed to be placed to the inside of the foot. They may be positioned to the outside based on physician preference or individual convenience of application.



2. Holding the lower leg, gently slide the foot into place until the heel is secure against the back and bottom of the AFO. Socks that cover the foot and lower leg are required to prevent skin contact with the AFO.



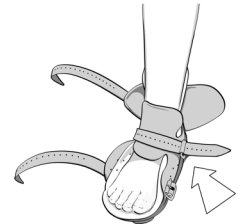
The exact position of the heel in the AFO will vary depending on the type and severity of the clubfoot. Forcing the heel into position can lead to sores, so check with your physician to verify the proper position.



3. Pull tongue horizontally against the ankle and hold in place with your thumb. Be sure the hole in the tongue is set in the center of the ankle, above the middle strap.



4. Buckle the middle strap securely over the horizontal tongue. Securely buckle the ankle strap but be careful not to overtighten, as that can lead to skin irritation and sores.



5. Look through the heel opening at the back of the AFO to ensure the heel is ideally down and to the back of the AFO. The heel may not initially be able to contact the bottom of the AFO after the tenotomy and last casting but will over time. If you do not see the heel in the window, readjust the tongue and middle strap so that the heel is properly positioned.



In some cases, the heel will not touch the bottom of the AFO, and in others the heel will be barely visible through the heel opening. In these challenging cases, the heel will drop over time as long as ankle motion is adequate. Forcing the heel into the AFO and overtightening the middle strap can lead to skin irritation, sores, and reduced bracing compliance.



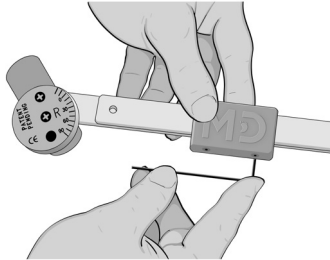
6. Once upper straps are tight and heel is securely in place, buckle the toe strap and retighten the other straps if needed.



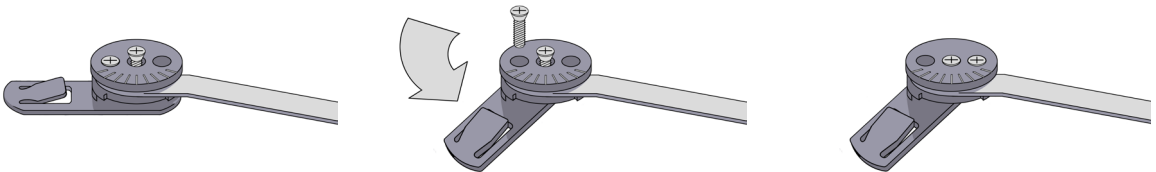
4.3 Ponseti® Abduction Bar

The bar should be set so that the width of the bar is equal to - or even slightly wider than - the shoulder width of the child. Measure the shoulder width of the child from the outside left shoulder to the right outside shoulder. Adjust the length of the bar from mid-heel of the left footplate to mid-heel of the right footplate so that it is equal to the shoulder width measurement.

1. Use the enclosed hex key to loosen set screws in bar lock. Adjust the width of the bar to the child's shoulder width, using the center screw in the heel cap as a guide. Re-tighten the set screws in the bar lock.



2. Using a screwdriver, loosen center screw of heel cap; remove outer screw. Rotate clip to desired degree indicator to set external rotation as determined by your physician. Re-insert outer screw into appropriate hole. Tighten both screws.



3. Insert clip into sole of AFOs until you hear a "click" - there will be an audible click when they are seated properly. Verify that the bar lock and Quick Clips are engaged when assembled by pulling on the AFO to make sure it does not disconnect from the bar. If damage is found discontinue use and Contact Customer Service.

5 PREPARATION

5.1 How to Transport and Store the Product

The **Mitchell Ponseti® Ankle Foot Orthotic** and the **Ponseti Abduction Brace** ship at room temperature and require no special handling during transport or storage.

6 MAINTENANCE

6.1 Reusing the Device


All parts were designed to be used by a single patient under normal use conditions and as prescribed by a physician.

Normal use includes the daily application of the AFO and **Ponseti® Abduction Bar** and use up to 23 hours per day, or as prescribed.

6.1.1 Cleaning the device


To clean the device:

1. Hand or machine-wash the AFO using cool water, a gentle cycle and mild detergent.
2. Let the AFO air dry completely before use.

 Do not use hot water when washing the **Mitchell Ponseti® Ankle Foot Orthotic**. This may cause the synthetic suede straps to warp, shrink, separate or delaminate. Do not put the AFO into a mechanical dryer. Air dry only.

6.2 How to Inspect the Product

The **Mitchell Ponseti® Ankle Foot Orthotic (AFO)** and **Ponseti® Abduction Bar** should be inspected every time for proper fit, manufacturing defect, and damage prior to the device being placed onto the child's feet.

 Carefully inspect the **Mitchell Ponseti® Ankle Foot Orthotic (AFO)** and **Ponseti® Abduction Brace** before each use. Never use an AFO or bar that is damaged, broken or not functioning properly, as this may injure your child and/or render treatment ineffective. Contact Customer Service for Support, if needed.

7 TROUBLESHOOTING

7.1 How to Identify and Solve Problems

7.1.1 Troubleshooting by non-skilled persons

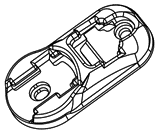
Error	Cause	Solution
Child develops blisters or other damage to the skin	Improper fit and/or use	Contact your physician or healthcare provider
Broken AFO (within 6 months of wear)	Manufacturing defect or damaged via normal use	Contact your point of purchase
Broken AFO (after 6 months of wear)	Damaged via normal use	Contact your point of purchase
Broken Bar, Quick Clip Connector, Heel Cap or Bar Lock	Damaged via normal use	Contact your point of purchase
Incorrect Size (within 7 days of receipt)	Sizing Error	Contact your point of purchase

7.2 Frequently Asked Questions

Question	Answer
Do the buckles go to the inside of the foot or to the outside of the foot?	The AFO was designed with the buckles set to the inside of the foot. This design feature is to aid parents in the donning and doffing of the AFOs. Ponseti experts do allow buckles to the outside of the foot based on professional preference or customer convenience. It will not alter the performance or risk of injury by orienting the buckles outward.
I just received my order, and the AFOs seem too big/too small. Is there a different size that would work better?	Contact your point of purchase
The child's heel is not down in the AFO. Is something wrong?	If the heel is not visible in the heel opening, check with your physician to ensure the clubfoot is fully corrected. If the physician indicates that the correction is good, it may not be necessary to force the heel down into the AFO, as this can lead to skin irritation, bracing discomfort, and reduced bracing compliance.
How long will each pair of AFOs last?	On average, an AFO will last 3-9 months. Some children grow rapidly and will need new AFO's within three months. As the child's growth rate slows, more time can be expected from each AFO.
How long will the bar last?	The bars are adjustable and should last approximately 2-3 iterations of AFOs. The bar width should be periodically checked and adjusted to match the child's shoulder width or as recommended by your physician or orthotist.

8 APPENDIX I – OPTIONAL ACCESSORIES














8.1 Optional accessories

Image	Name	Description
	Adapter	Universal mount that provides the convenience of the Ponseti® Quick Clip System when utilizing an alternative AFO. This allows the customer to attach a wide range of corrective AFOs to the Ponseti® Abduction Bar

9 GLOSSARY

Term	Meaning
Ankle Foot Orthosis (AFO)	An AFO is a brace, usually made of plastic, that is worn on the lower leg and foot to support the ankle, hold the foot and ankle in the correct position
Casting	A procedure to keep the clubfoot in place after manipulation. Padding is wrapped around the foot, then plaster is applied, and the cast is molded into place.
Clubfoot (talipes)	Clubfoot (Talipes equinovarus) is a common birth defect in which the foot is twisted out of shape or position. In clubfoot, the foot appears twisted and can even look as if it's upside down. Despite its appearance, clubfoot itself doesn't cause any discomfort or pain. Treatment is usually successful and includes stretching and casting (Ponseti Method) or stretching and taping (French method). Sometimes, surgery is needed.
Dorsiflexion	Dorsiflexion is the flexion of the foot in an upward direction, from the ankle.
Equinus	Equinus is a condition in which the upward bending motion of the ankle joint is limited. Someone with equinus lacks the flexibility to bring the top of the foot toward the front of the leg. Equinus can occur in one or both feet.
Foot Abduction Brace	Abduction is a motion that pulls a structure or part away from the midline of the body. An abduction brace keeps the foot in proper alignment with the midline.
Orthotist	An orthotist is a healthcare professional who makes and fits braces and splints (orthoses) for people who need added support for body parts that have been weakened by injury, disease, or disorders of the nerves, muscles, or bones
Ponseti Method	The Ponseti Method is a non-surgical clubfoot treatment process developed by Dr. Ignacio Ponseti. The method utilizes gentle manipulation and casting to gradually move the foot into the correct position.
Pressure Saddles	A pressure saddle is a piece of soft, flexible rubber that attaches to the middle strap of the AFO to provide additional relief from the pressure of the strap.
Tenotomy	An Achilles tendon release, also known as tenotomy, is a surgical procedure that involves cutting through the Achilles tendon to allow for final dorsiflexion of the foot. The procedure is used to correct the equinus deformity seen in clubfoot.

10 ICON LEGEND

Icon	Meaning	Icon	Meaning
	Ankle-Foot Orthotic (AFO)		Caution
	Authorized Representative in the European Community		Date of manufacture
	Manufacturer		Importer of record
	Single Patient, Multiple Use		Non-sterile
	Indicates Item is a Medical Device		Catalog number
	CE Mark (in compliance with Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on Medical Devices)		Batch code
	Consult Instructions for Use		